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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,474	07/19/2001	John F. Boylan	01017/36524A	7250

4743 7590 02/05/2004

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EXAMINER	
MONSHIPOURI, MARYAM	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 02/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/909,474	BOYLAN ET AL.	
	Examiner	Art Unit	
	Maryam Monshipouri	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-76* is/are pending in the application.

4a) Of the above claim(s) *9,12-52,56-67 and 70-74* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,10,11,53-55,68,69,75 and 76* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) Filed 4/2/02
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

Applicant's response to restriction requirement filed 1/10/2003, is acknowledged. Applicant elected Group I invention directed to claims 1-8, 10-11, 53-55, 68-69 and 75-76 with traverse. Claims 9, 12-52, 56-67 and 70-74 are withdrawn as drawn to non-elected invention.

In traversal of restriction requirement applicant argues that the examiner has not established that a serious burden would be imposed on the patent Office if all 76 claims were searched and examiner together. According to applicant, the polypeptide of Group II is encoded by the polynucleotide of Group I. It is probable that a search based on the polypeptide of Group II will involve the same prior art search compared to search based on DNA of Group I. Further, in view of applicant search engines permit a searcher to search translations of known DNA in all reading frames automatically, permitting rapid comparisons of DNA and polypeptide databases. The applicant also submits that it would not pose an undue burden of examining if the following inventions were additionally examined: Group VII, X, and XI because patentability of the DNA of Group I will establish novelty of these groups as well.

Applicant further indicates that he/she intends to formally request rejoinder of Groups VII, X, and XI under M.P.E.P. section 8212.04 if the claims of Group I are found allowable.

Therefore, based on the above arguments applicant submits that the examiner has failed to establish that a serious burden of searching and examination would be imposed if all 76 claims were rejoined together and restriction should be withdrawn.

These arguments were fully considered but were found **unpersuasive**. This is because, even though, as applicant indicates, there may be some overlap between the prior art sequence searches required for Groups I and II, the overall searches, which include key work and classification search for each invention, are **not coextensive**. For example, the search for Group I invention requires a search in class 536/23.2, which is totally unnecessary for Group II invention. Similarly, the search required for Group II invention requires a search in class 530/350 which is irrelevant to Group I invention. Therefore, in contrast to applicant's view, rejoinder of Groups I-II does impose an undue burden of searching on the examiner. Further, said imposition is not a probability but a certainty.

With respect to rejoinder of Groups VII, X and XI with Group I invention, the examiner agrees that the novelty determination of Group I invention would have an impact on the novelty determinations of said inventions, but the examination of said Groups beyond establishment of novelty, involves issues such as enablement, written description, indefiniteness etc. which, upon rejoinder, do impose an undue burden of examination on the examiner.

Finally, Group I invention is not allowable as shown below. Thus, rejoinder of Groups VII, X and XI under MPEP section 821.04 is currently impossible.

In conclusion, in view of the above response provided to applicant's arguments in addition to those provided previously, the restriction is maintained according to previous office action and is hereby made **Final.**

DETAILED ACTION

Claims 1-8, 10-11, 53-55, 68-69 and 75-76 are under examination on the merits. Claims 9, 12-52, 56-67 and 70-74 are withdrawn as drawn to non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8, 10-11, 53-55, 75-76 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "an activity" in claims 1-3 is unclear. The only activity of SEQ ID NO:2 that is disclosed in the specification is kinase activity. Thus, **for examination purposes it is assumed that by referring to "an activity" applicant is referring to kinase activity only.**

If applicant by using said term is referring to other activities beyond kinase activity he/she should indicate them in response to this office action. Claims 4-8, 10-11, 53-55 and 75-76 are rejected for depending from rejected base claims 1-3.

Claims 1-2, 4-8, 10-11, 53-55, 75-76 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term " moderately or highly stringent conditions" in claims 1-8, 10-11, 53-55, and 75-76 is unclear. Applicant has not specifically, defined said conditions in the specification in terms of salt and temperature conditions used. In pages 21-22 some examples of possible high or moderate stringent conditions are provided but said conditions are not specific to said

term. In the absence of clear recitation of salt and temperature conditions used for hybridization (both high and moderate) into claims 1-2, the skilled artisan does not know how to obtain the claims DNA sequences. Claims 4-8, 10-11, 53-55 and 75-76 are rejected merely for depending from the rejected base claims 1-2.

Claims 68-69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "variant" in claim 68 and its dependent claim 69 is unclear. It is not clear what variants beyond splice variants and allelic variants applicant is referring to.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 3,11 and 68-69 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for DNA sequences encoding SEQ ID NO:2, does not reasonably provide enablement for any of the following:

DNA sequences encoding a polypeptide that exhibits 70% identity to SEQ ID NO:2, where said polypeptide has the same activity as SEQ ID NO:2 (i.e. kinase activity, see the 112 second rejection, above).

- DNA fragments of SEQ ID NO:1, (a) or (b), encoding a polypeptide of at least 25 amino acid residues wherein the polypeptide retains kinase activity.

- DNA sequences encoding a polypeptide that has substitutions and/or deletions of 1-358 amino acid residues of SEQ ID NO:2, wherein said polypeptide retains kinase activity.
- Reagents comprising a DNA sequence encoding fragments, allelic variants, splice variants and homologs of SEQ ID NO:2 with no specific activity.
- DNA fragments of SEQ ID NO:1, comprising at least 16 bases, wherein said DNA sequence does not encode a product with kinase activity.
- DNA sequences complementary to the above products.

The criteria for undue experimentation, summarized in *re Wands*, 8, USPQ2n 1400 (Fed. Cir. 1988) are: 1) the quantity of experimentation necessary, 2) the amount of direction or guidance presented, 3) the presence and absence of working examples, 4) the nature of the invention, 5) the state of prior art, 6) the relative skill of those in the art, 7) the predictability or unpredictability of the art, and 8) the breadth of the claims.

The specification fails to teach which critical bases in above products must be retained in order to encode a product with kinase activity. No examples of the above products or their critical residues are provided either. Current state of prior art indicates that a DNA product that retains 70% identity to SEQ ID NO:2, retains a sequence capable of encoding merely 25 amino acids of SEQ ID NO:2, enodes a variant of SEQ ID NO:2 wherein residues 1-358 are substituted and/or deleted, encodes allelic or splice variants of SEQ ID NO:2 with no specific activity or complementary sequences thereof are not necessarily capable of encoding a product with appropriate three dimensional structure to encode a product with kinase activity.

Therefore due to lack of sufficient teachings and examples provided in the specification and due to unpredictability of prior art as to which residues in above mentioned products must be retained in order to encode a product with the appropriate three dimensional structure to have kinase activity one of skill in the art has to go through the burden of undue experimentation in order to screen for DNA sequences that are within the scope of the disclosure and as such claims 2, 3 and 68 are not enabled.

Claims 11 and 69 are rejected for depending from rejected base claims 2 and 68.

Claims 2, 3, 11 and 68-69 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 2, 3 and 11 are directed to a the following **genera** of DNA sequences that are inadequately described in the specification:

Genus of DNA sequences encoding a polypeptide that exhibits 70% identity to SEQ ID NO:2, where said polypeptide has the same activity as SEQ ID NO:2 (i.e. kinase activity, see the 112 second rejection, above).

- Genus of DNA fragments of SEQ ID NO:1, (a) or (b), encoding a polypeptide of at least 25 amino acid residues wherein the polypeptide retains kinase activity.

- Genus of DNA sequences encoding a polypeptide that has substitutions and/or deletions of 1-358 amino acid residues of SEQ ID NO:2, wherein said polypeptide retains kinase activity.
- Genus of reagents comprising a DNA sequence encoding fragments, allelic variants, splice variants and homologs of SEQ ID NO:2 with no specific activity.
- Genus of DNA fragments of SEQ ID NO:1, comprising at least 16 bases, wherein said DNA sequence does not encode a product with kinas activity.
- Genera of DNA sequences complementary to the above products.

The specification does not contain any disclosure of either the structure or function of the following DNA sequences : those that retain 70% identity to SEQ ID NO:2 capable of encoding products with/without kinase function, those that retain a sequence capable of encoding merely 25 amino acids of SEQ ID NO:2 with/without function, those encoding a variant of SEQ ID NO:2 wherein residues 1-358 are substituted and/or deleted, those encoding allelic or splice variants of SEQ ID NO:2 with no specific activity or complementary sequences thereof.

The genera of DNAs that comprise these above DNA sequence are large variable genera of retaining diverse structures with the potentiality of encoding many different proteins. Therefore, many structurally and/or functionally unrelated DNAs are encompassed within the scope of these claims, including partial DNA sequences. The specification discloses only a **single species** for each claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all

species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Claims 69 and 11 are rejected for depending from rejected base claims 68 and 2.

Applicant is referred to the revised interim guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-8, 10-11, 53-55, 68-69, 75 are rejected under 35 U.S.C. 102(a) as being anticipated by Virca et al. (U.S. Patent No. 6,387,676). Virca teaches a DNA sequence (see their SEQ ID NO:3) encoding kinase, matching residues 300-1006 of SEQ ID NO:1 of this invention completely (see the attached sequence alignment) prior to this invention, and thus can hybridize to SEQ ID NO:1, under moderately or high stringent conditions (anticipating claims 1-2, and 11). Said sequence does comprise at least 16 nucleotides of SEQ ID NO:12, anticipating claim 3. Virca teaches and claims vectors, host cells (prokaryotic, viral and eukaryotic) comprising it's DNA, anticipating claims 4-7 and 55. It also claims methods of recombinantly expressing its DNA (see claim 8), anticipating claims 8, 10 of this invention.

Virca also teaches about pharmaceutical compositions (see column 33) and diagnostic or therapeutic agents comprising its polypeptide and its encoding DNA, which can be attached to a solid support (see claims 53-54, and 75).

Claims 1-8, 10-11, 53-55, 68-69, 75-76 are rejected under 35 U.S.C. 102(a) as being anticipated by Tang et al. (US2002/0197679, 12/26/2002). Tang discloses a DNA sequence encoding kinase that displays 97% overall homology to SEQ ID NO:1 of this invention (see the attached alignment) and thus can hybridize to SEQ ID NO:1, under moderately or high stringent conditions (anticipating claims 1-2, and 11). Said sequence does comprise at least 16 nucleotides of SEQ ID NO:12, anticipating claim 3. Tang teaches vectors, host cells (prokaryotic and eukaryotic) comprising it's DNA, anticipating claims 4-7 and 55. It also teaches methods of recombinantly expressing its DNA, anticipating claims 8, 10 of this invention (see page 4).

Tang also teaches about pharmaceutical compositions (see pages 24-28) and diagnostic or therapeutic agents comprising its polypeptide and its encoding DNA, which can be attached to a solid support (anticipating claims 53-54, and 75) as well as arrays comprising its DNA sequence (see page 24) , anticipating claim 76.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is ((571) 272-0932. The examiner can normally be reached on 7:00 a.m to 5:30 p.m. except for Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnanthapu Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

MARYAM MONSHIPOURI, PH.D.
PRIMARY EXAMINER

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